60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20160012A **DATE:** 13 March 2018

PROTOCOL TITLE: Accelerating Coagulation in Traumatic Injuries Using Inorganic Polyphosphate-Coated Silica Nanoparticles in a Swine (*Sus scrofa*) Model.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Capt Anders Davidson

DEPARTMENT: SGSE **PHONE #:** 507-828-8804

INITIAL APPROVAL DATE: 21 July 2016 **LAST TRIENNIAL REVISION DATE:** 20 July 2017

FUNDING SOURCE:

1. RECORD OF ANIMAL USAGE:

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	**24**	**6**	**20**

2. PROTOCOL TYPE / CHARACTERISTICS: (Check all applicable terms in **EACH** column)

___ Training: Live Animal ___ Medical Readiness ___ Prolonged Restraint

___ Training: non-Live Animal ___ Health Promotion ___ Multiple Survival Surgery

___ Research: Survival (chronic) ___ Prevention ___ Behavioral Study

_X_ Research: non-Survival (acute) ___ Utilization Mgt. ___ Adjuvant Use

___ Other ( ) ___ Other (Treatment) ___ Biohazard

3. PROTOCOL PAIN CATEGORY (USDA): (Check applicable) ___ C _X_ D ___ E

4. PROTOCOL STATUS:

***Request Protocol Closure:**

___ Inactive, protocol never initiated

___ Inactive, protocol initiated but has not/will not be completed

_X_ Completed, all approved procedures/animal uses have been completed

5. Previous Amendments:
List all amendments made to the protocol. **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
1	26 Oct 16	Personnel
2	20 Jul 17	Personnel

6. FUNDING STATUS: Funding allocated: $36,120.00 Funds remaining: $0.00

7. PROTOCOL PERSONNEL CHANGES:

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? __X_ Yes ___ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

NAME	PROTOCOL FUNCTION	IACUC APPROVAL
Guillaume Hoareau, DVM, PhD	AI	Yes
Austin Johnson, MD, PhD	AI	Yes
Capt Carl Beyer	AI	Yes
Capt Harris Kashtan	AI	Yes
Capt Andrew Wishy	AI	Yes

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

NAME	PROTOCOL FUNCTION	DATE OF DELETION
Maj Erik DeSoucy	AI	20 July 2017
Capt Emily Tibbits	AI	20 July 2017
Capt Meryl Simon-Logan	AI	20 July 2017

8. PROBLEMS / ADVERSE EVENTS: Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

None.

9. REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No.

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No.

10. PUBLICATIONS / PRESENTATIONS: (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

None.

11. PROTOCOL OBJECTIVES: (Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?)

Yes. The protocol was completed without any adverse events. Although not statistically significantly different, there was a trend towards less blood loss in animals that had received nanoparticles.

12. PROTOCOL OUTCOME SUMMARY: (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

Objective: To determine if silica-based platelet-like nanoparticles (PLNP) administered prior to liver injury will decrease blood loss in a swine in a swine model.

Methods: 9 male and 4 female pigs weighing 65±8 kg were anesthetized and instrumented. After abdominal exposure they were randomized to receive either PLNP or normal saline. After 10 minutes, the left lateral liver lobe was sharply dissected with trauma shears and the cut surface area was measured. Pressure was applied using hand pressure and 3 lap pads. Three minutes later pressure was released, a suction drain placed, and the abdomen was closed with towel clamps. The study ended after 1 hour. The cut liver lobe was clamped with Doyen forceps and the animal was euthanized. Lap sponges and all free blood and clots were carefully removed and weighed. Liver samples were obtained for histopathology review.

Results: There were no significant differences between the PLNP and control groups in any baseline characteristics, including preoperative blood loss and liver injury surface area. Pigs receiving PLNP averaged 13.5 mL of blood lost per kg vs. controls who averaged slightly more blood loss (22.8 mL/kg), but the difference was not significant ($p = 0.12$). There were no significant differences between groups in physiologic measures, lab studies, or histopathology evaluation at the end of the study.

Conclusion: Based on these results, we conclude there was no significant difference in blood loss between controls and pigs receiving PLNP. There was no evidence of thrombus formation in any of the tissues examined.

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ANDERS J. DAVIDSON, Capt, USAF, MC **(Date)**
Primary Investigator

Attachments:
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

Attachment 1

Defense Technical Information Center (DTIC) Abstract Submission

This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Objective: To determine if platelet-like nanoparticles (PLNP) will decrease blood loss in a swine in a swine model.

Methods: Pigs were anesthetized and instrumented and randomized to receive either PLNP or normal saline. After 10 minutes, the left lateral liver lobe was sharply dissected with trauma shears. Pressure was applied using hand pressure and 3 lap pads. Three minutes later pressure was released and a suction drain placed. The study ended after 1 hour. The cut liver lobe was clamped and the animal was euthanized. Lap sponges and all free blood and clots were carefully removed and weighed.

Results: There were no significant differences between the groups in any baseline characteristics, preoperative blood loss, or liver injury surface area. Pigs receiving PLNP lost 13.5 mL of blood per kg vs. controls who averaged 22.8 mL/kg, but the difference was not significant. There were no significant differences between groups in physiologic measures, lab studies, or histopathology evaluation at the end of the study.

Conclusion: Based on these results, we conclude there was no significant difference in blood loss between controls and pigs receiving PLNP. There was no evidence of thrombus formation in any of the tissues examined.

Grant Number:_____

From:_____

****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**